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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 08/533,895 09/26/95 TOPALIAN 9 2026-4205 **EXAMINER** HM12/0818 PATENT BRANCH WEATHERSPOON, J PAPER NUMBER **ART UNIT** OFFICE OF TECHNOLOGY TRANSFER NATIONAL INSTITUTES OF HEALTH BOX 13 6011 EXECUTIVE BOULEVARD SUITE 325 1645 ROCKVILLE MD 20852 DATE MAILED: 08/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

## Office Action Summary

Application No. 08/533,895 Applicant(s)

Examiner

John K. Weatherspoon

Topalian et al

Group Art Unit 1645

🛛 Responsive to communication(s) filed on May 21, 1999	·
☑ This action is FINAL.	
☐ Since this application is in condition for allowance except for accordance with the practice under <i>Ex parte Quayle</i> , 193	
A shortened statutory period for response to this action is set is longer, from the mailing date of this communication. Failure application to become abandoned. (35 U.S.C. § 133). Extens 37 CFR 1.136(a).	e to respond within the period for response will cause the
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
☐ Claim(s)	is/are allowed.
	is/are rejected.
Claim(s)	is/are objected to.
☐ Claims	are subject to restriction or election requirement.
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawi	ng Review, PTO-948.
☐ The drawing(s) filed on is/are objection	cted to by the Examiner.
☐ The proposed drawing correction, filed on	is 🗀 approved 🗀 disapproved.
$\hfill\Box$ The specification is objected to by the Examiner.	
$\hfill\Box$ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
$\square$ Acknowledgement is made of a claim for foreign priority	y under 35 U.S.C. § 119(a)-(d).
☐ All ☐ Some* ☐ None of the CERTIFIED copies	of the priority documents have been
received.	
received in Application No. (Series Code/Serial No.	
$\square$ received in this national stage application from th	e International Bureau (PCT Rule 17.2(a)).
*Certified copies not received:	
☐ Acknowledgement is made of a claim for domestic prior	rity under 35 U.S.C. 3 119(e).
Attachment(s)	
Notice of References Cited, PTO-892	
☐ Information Disclosure Statement(s), PTO-1449, Paper	No(s)
☐ Interview Summary, PTO-413	248
<ul><li>☐ Notice of Draftsperson's Patent Drawing Review, PTO-S</li><li>☐ Notice of Informal Patent Application, PTO-152</li></ul>	740
□ Notice of informal Fatent Application, 1 10-132	
SEE OFFICE ACTION ON	THE FOLLOWING PAGES

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#### **DETAILED ACTION**

1. Applicants amendment and response dated 5/21/99 has been entered into the record as Paper No.24. Claims 64-92 are pending and under examination.

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. The previous objections to claims 64-67, 69-79 and dependent claims thereof, i.e. claims 80-81, 83-87 and 89-92 are withdrawn in view of applicants amendment.

## Claim Rejections - 35 USC § 112 first paragraph

4. New grounds of rejection: In view of applicants amendment and response to the previous rejection of claims 68, 71, 76, 79, 82, 85, 88 and 91-92 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, applicants have amended said claims to recite the peptide sequences "X<sub>1</sub>LLSNX<sub>2</sub>PLG and X<sub>1</sub>LQDSX<sub>2</sub>PDS". Applicants argue on pages 5-6 of applicants response that the instant specification provides sufficient written description support for said claim amendments, e.g. applicants maintain (page 5 of response) that "the sixth position [of the claimed amino acid sequences] may be any hydrophobic [i.e. nonpolar] amino acid" and that "the fourth position of the peptide may be any hydrophobic [i.e. nonpolar]

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amino acid or aspartic or glutamic acid". Applicants arguments have been fully considered but are not deemed to be persuasive for the following reasons.

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One skilled in the art recognizes, for example, that since said claims as amended are drawn to "X<sub>1</sub>LLSNX<sub>2</sub>PLG and X<sub>1</sub>LQDSX<sub>2</sub>PDS" wherein "X<sub>2</sub> [i.e. the sixth position] is selected from the group consisting of methionine, leucine, threonine, isoleucine, serine and valine", and in view of the teachings of Bohinski et al (see entire Bohinski et al reference, cited on PTO-892) i.e. with regard to polar versus nonpolar amno acids, serine and threonine (i.e. position X2, equivalent to the sixth position of the claimed amino acid sequences) are hydrophilic (i.e. polar) amino acids instead of claimed "hydrophobic [i.e. nonpolar]" amino acids. Further, one skilled in the art recognizes that, wherein said claims recite that "the fourth position of the peptide may be any hydrophobic [i.e. nonpolar] amino acid or aspartic or glutamic acid", and in view of claimed "X<sub>1</sub>LLSNX<sub>2</sub>PLG and X<sub>1</sub>LQDSX<sub>2</sub>PDS", i.e. wherein S (serine) and D (aspartic acid) constitute the fourth positions of the claimed peptides, one skilled in the art recognizes that serine is a hydrophilic (i.e. polar) amino acid instead of claimed "hydrophobic [i.e. nonpolar]" amino acid. Thus applicants arguments (pages 5-6 of applicants response) that the original specification provides support for said amended claims is not persuasive, and said claims are recognized as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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5. With regard to the previous rejection of claims 64-92 under 35 USC 112, first paragraph (see paragraph/item number 6 on pages 4-6 of the previous Office Action mailed 1/25/99), applicants have provided no response for said rejection in applicants amendment and response dated 5/21/99. Further, since claims 64-92 as amended do not overcome the basis for said rejection as set forth in the previous Office Action, i.e. that modifications of a peptide will affect the biological activity of said peptide, said rejection is maintained for claims 64-92.

## Claim Rejections - 35 USC § 112 second paragraph

6. With regard to the previous rejection of claims 69-79 under 35 U.S.C. 112, second paragraph (as set forth on page 6 pf the previous Office Action), applicants have provided no response for said rejection in applicants amendment and response dated 5/21/99; thus said rejection is maintained for claims 69-79.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on

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the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Status of Claims**

## 7. No claim is allowed.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1645 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Weatherspoon, Ph.D. whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (703) 308-3995.

John Weatherspoon, Ph.D. August 10, 1999

Anthony Caputa, Ph.D.

Supervisory Primary Examiner

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